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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte COLIN CRAIG McCULLOCH, CHRISTOPHER J. SEVINSKY, and FIONA GINTY

Appeal 2016-001180 Application 13/252,072¹ Technology Center 1600

Before DONALD E. ADAMS, RACHEL H. TOWNSEND, and

DEVON ZASTROW NEWMAN, Administrative Patent Judges.

TOWNSEND, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of and system for analyzing tissue features, which have been rejected as being directed to patent ineligible subject matter and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

Studying tissue specimens using labelled antibodies or antibody surrogates as biomarkers is well known, including testing "for the

¹ Appellants identify the Real Party in Interest as the General Electric Company. (Appeal Br. 2.)

"expression of numerous biomarkers." (Spec. $\P\P 3, 5.$) "The techniques of tissue treatment and examination have been refined so that the level of expression of a given biomarker in a particular cell or even a compartment of the given cell such as the nucleus, cytoplasm or membrane can be quantitatively determined." (Id. at $\P 4.$) "Commonly the treated tissue is examined with digital imaging and the level of different signals emanating from different biomarkers can consequently be readily quantified." (Id.) According to Appellants, the claimed invention "involve[s] distinct processes for analyzing a dataset." (Id. at $\P 16.$)

Claims 1, 2, 6–15, 17, 18, and 21–30 are on appeal.² Claims 1 and 17 are representative and read as follows:

1. A method of analyzing tissue features based on multiplexed biometric images comprising:

receiving cell profile data comprising multiplexed biometric images capturing the expression of a plurality of biomarkers with respect to a field of view in which individual cells are delineated and segmented into compartments;

assigning respective individual cells in the field of view to respective single clusters of a plurality of clusters of similar cells in a selected set of clusters, wherein each cluster in the selected set of clusters comprises cells having a plurality of selected attributes more similar to the plurality of selected attributes of other cells in that cluster than to the plurality of selected attributes of cells in other clusters in the set such that at least two individual cells in the field of view may be assigned to different clusters;

determining a proportion of the cells assigned to each cluster in the selected set of clusters;

² Claims 16 and 31–35 are also pending but have been withdrawn from consideration. (Appeal Br. 19 and 23–24.)

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> generating and displaying a montage of the first cell wherein the montage comprises a portion of a plurality of the multiplexed biometric images of the first cell's expression of the plurality of biomarkers; and

> determining a diagnosis, a prognosis, or a response to treatment of a condition or a disease based on the proportion and a known association of the selected set of clusters with at least one piece of meta-information including a field of view level assessment or a patient-level assessment.

(Appeal Br. 15–16.)

17. A system for analyzing tissue features based on multiplexed biometric image data comprising:

a storage device storing cell profile data comprising multiplexed biometric images capturing the expression of a plurality of biomarkers with respect to a field of view in which individual cells are delineated and segmented into compartments;

and at least one processor for executing code that causes the at least one processor to perform the steps of:

accessing the cell profile data;

assigning respective individual cells in the field of view to respective single clusters of a plurality of clusters of similar cells in a selected set of clusters, wherein each cluster in the selected set of clusters comprises cells having a plurality of selected attributes more similar to the plurality of selected attributes of other cells in that cluster than to the plurality of selected attributes of cells in other clusters in the set such that at least two individual cells in the field of view may be assigned to different clusters;

determining a proportion of the cells assigned to each cluster in the selected set of clusters;

generating and displaying a montage of an individual cell in a first cluster of the selected set of clusters, wherein the montage comprises a portion of a plurality of the multiplexed biometric images of the individual cell's expression of the plurality of biomarkers; and

determining a diagnosis, a prognosis, or a response to treatment of a condition or a disease based on the proportion and a known association of the selected set of clusters with at least one piece of meta-information including a field of view level assessment or a patient-level assessment.

(Appeal Br. 19–20.)

The following grounds of rejection by the Examiner are before us on review:

- 1. Claims 1, 2, 6–15, 17, 18, and 21–30 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.
- 2. Claims 1, 2, 6–10, 13–15, 17, 18, 21–25, and 28–30 under 35 U.S.C. § 103(a) as unpatentable over Gough³ and Hunter.⁴
- 3. Claims 11, 12, 26, and 27 under 35 U.S.C. § 103(a) as unpatentable over Gough, Hunter, and Theodoridis.⁵

DISCUSSION

Patent Ineligible Subject Matter

The Examiner finds that the claimed method is an abstract idea that fails to meet the standard for statutory eligibility because the method, which involves tissues and cells, concerns data manipulation steps pertaining to collected information from cells without transforming the cells or being tied to any particular machine. (Ans. 2; Final Action 4.) Similarly, the Examiner

³ Gough et al., US 2009/0298703 A1, published Dec. 3, 2009.

⁴ Hunter et al., US 2008/0144895 A1, published June 19, 2008.

⁵ Sergios Theodoridis & Konstantinos Koutroumbas, *Pattern Recognition: Chapter 14: Clustering Algorithms III* 631–35 (Academic Press, 2006).

finds that the claimed system does not "amount to significantly more than the abstract idea of an algorithm that analyzes biometric images." (Ans. 3; Final Action 5.) The Examiner indicates that the claims recite "generic computer structures (*e.g.*[,] 'a storage device' and a 'processor') that perform only well-understood, routine and conventional acts in the art" and that, viewed individually and as a whole, the method "do[es] not provide meaningful limitations to transform the abstract idea" (*Id.*)

We agree with the Examiner's factual findings and conclusion that the method and system claims on appeal are patent ineligible abstract ideas.

a. Abstract Idea

Appellants' argument that the claims are not an abstract idea because analyzing biometric images is not "a fundamental economic practice, a method of organizing human activities, an idea 'of itself,' or a mathematical relationship/formula" (Reply Br. 3), is unavailing. "[T]he category of abstract ideas is not limited to economic or commercial practices or methods of organizing human activity." *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1313 (Fed. Cir. 2016).

"The Supreme Court has not 'delimit[ed] the precise contours of the 'abstract ideas' category." *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1346 (Fed. Cir. 2014) (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2357 (2014)). Our reviewing Court has held "information as such is an intangible" and thus, has "treated collecting information, including when limited to particular content (which does not change its character as information), as within the realm of abstract ideas." *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (collecting cases).

Likewise it has "treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category." *Id.* at 1354 (collecting cases). And, it has "recognized that merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis." *Id.* (collecting cases).

The method at issue concerns a multistep process that starts with receiving image data from the expression of cell biomarkers and ends with determining "a diagnosis, a prognosis, or a response to treatment of a condition or a disease" based on organization of that data. The analytics recited to make the determination require an assignment based on observed characteristics, assessing a "proportion" based on the assignment, and generating a montage of images from the received data. In short, the method collects information and analyzes it and does nothing to change its character as collected information; the collected information is simply organized in a particular way to display it in a particular way. The system claims are similar in that they include a storage device to store data, and a "processor for executing code that causes the at least one processor to perform" the steps that are also recited in the process claims. We agree with the Examiner that these claims fall into the category of an abstract idea. See, e.g., Elec. Power Grp., 830 F.3d at 1353–54 (explaining that an invention directed to collection, manipulation, and display of data was an abstract process); Content Extraction, 776 F.3d at 1346–47 (finding with respect to method claims that "1) collecting data, 2) recognizing certain data within the collected data set, and 3) storing that recognized data in a memory" is an

abstract idea and explaining that is because "[t]he concept of data collection, recognition, and storage is undisputedly well-known. Indeed, humans have always performed these functions").

We find, similar to what our reviewing Court found in *Electric Power*, the claimed method and system is not an improvement in computers as tools but are abstract ideas that use computers as tools. *Elec. Power*, 830 F.3d at 1354.

b. No inventive concept beyond the claimed abstract idea

Because we find the claims on appeal are directed to an abstract idea, we turn to the second step in the framework set forth by the Supreme Court in *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289 (2012), and *Alice Corp. Pty. Ltd.*, 134 S. Ct. 2347, for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355. Step two is "a search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id.* (internal quotations, brackets, and citation omitted). In the second step, we examine the elements of the claim to determine whether the claim contains an inventive concept sufficient to "transform" the claimed abstract idea into a patent eligible application. *Mayo*, 132 S. Ct. at 1294. We conclude that neither the practice of the method claims nor the system claims result in such an inventive concept.

As our reviewing court recently noted, "[p]recedent has recognized that specific technologic modifications to solve a problem or improve the functioning of a known system generally produce patent-eligible subject

matter." *Trading Techs. Int'l, Inc. v. CQG, Inc.*, Appeal No. 2016-1616, 2017 WL 192716, at *3 (Fed. Cir. Jan. 18, 2017) (non-precedential). Thus, for example "[a]bstraction is avoided or overcome when a proposed new application or computer-implemented function is not simply the generalized use of a computer as a tool to conduct a known or obvious process, but instead is an improvement to the capability of the system as a whole." *Id.* at 8 (citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016)). On the other hand, "ineligible claims generally lack steps or limitations specific to solution of a problem, or improvement in the functioning of technology." *Id.*

Notwithstanding that the claims require the use of "specialized machines," i.e., "specialized image acquisition machines and imaging hardware" (Reply Br. 4), we find the claimed invention is much like the method claims found to be directed to patent ineligible subject matter in Mayo in that "[t]he upshot [of the claimed method] is that the . . . [recited] steps simply tell doctors to gather data from which they may draw an inference in light of the correlations." Mayo, 132 S. Ct. at 1298. The system claims merely append generic computer elements, i.e., a storage device and a processor to effect the analytics. We find the claimed "steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." Id.

Appellants' arguments to the contrary are unavailing. Appellants argue that the claims are not directed to an abstract idea because the method improves the analysis of medical images by "improving determination of cell similarity based on cell attributes in the context of several possible attributes." (Appeal Br. 7–8.) According to Appellants,

[p]articular clusters of biomarker expression may be associated with particular disease prognosis. However, it may be difficult to determine how to sort such clusters and to determine how many groups should be generated. Too few groups may result in cells with distinctive characteristics being grouped together, while too many groups may result in complicated analysis.

(Appeal Br. 7.) Appellants explain that "assigning an individual cell to a cluster based on the recited steps and then generating and displaying a montage of expression of biomarkers from a plurality of multiplexed images" offers "improvements in diagnosis without adding undesirable computational complexity via the designation of too many clusters" and also "improve[s] the functioning of a computer performing the recited method or a system as recited." (*Id.* at 9–10.)

We do not find this argument persuasive. "[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). "[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988). The recited process for analyzing image data is to assign cells to a cluster, determine a proportion of cells assigned to each cluster of a selected set of clusters, and generate and display a montage of images. In short, the process steps are recited at a very high level of abstraction, *i.e.*, generically. The system claims recite a generic storage device and processor that executes code to analyze the data.

As explained in Appellants' Specification "[e]xamination of tissue specimens that have been treated to reveal the expression of biomarkers is a known tool for biological research and clinical studies." (Spec. ¶ 3.)

"Commonly the treated tissue is examined with digital imaging and the level of different signals emanating from different biomarkers" is "readily quantified." (Id. at ¶¶ 4–14.) The known prior art processes include using computers to assist in storing collected information about the tissue specimen including the segmentation "of individual cell units and their subcellular compartments (including membrane, cytoplasm and nucleus)" (Id. at ¶ 9), "grouping . . . cells together which have similar biomarker expression attributes" (Id. at ¶¶ 10–11), "could be examined to identify any cell attribute which is associated with the diagnoses or prognoses of a given condition or disease or with the response to a given therapy for a given condition or disease," as well as "generat[ing] various expression profiles that are then overlaid on an image of the tissue of interest." (Id. at ¶¶ 7, 12.)

The steps involved in Appellants' generic process claims, like the prior art, analyze collected data without changing its character as collected information; the information is not transformed, it is simply organized into a new form (abstracted portions of stored images). Thus, while Appellants argue that the claims are analogous to the "Digital Image Processing" example provided by the USPTO with the 2014 Interim Eligibility Guidance (Appeal Br. 8–10; Reply Br. 6–8), we disagree. In that example, the information was transformed. As the Guidance notes:

The claim, when taken as a whole, does not simply describe the generation of a blue noise mask via a mathematical operation and receiving and storing data, but combines the steps of generating a blue noise mask with the steps for comparing the image to the blue noise mask and converting the resulting binary image array to a halftoned image. By this, the claim

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goes beyond the mere concept of simply retrieving and combining data using a computer.

(Subject Matter Eligibility Examples: Abstract Ideas: 3. Digital Image Processing at 8, available at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.)

For the same reason, we find that Appellants' claims are not analogous to those found patent eligible in *McRO*, *Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313–16 (Fed. Cir. 2016). Unlike in *McRO*, the claims on appeal are not limited to specific, claimed features of recited rules with specific characteristics that renders information into a specific format that is then used and applied to create desired results allowing for realization of computer automation that was not possible prior to the claimed invention. *See McRO*, 837 F.3d at 1313–16.

Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. "If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." *Parker v. Flook*, 437 U.S. 584, 595 (1978) (internal quotations omitted).

Digitech Image Tech's v. Elecs. for Imaging, 758 F.3d 1344, 1351 (Fed. Cir. 2014). The steps of the claims on appeal generically recite a process of combining data to determine a diagnosis, prognosis or response to treatment; it does not claim the use of that data to transform the collected data. Moreover, whether or not the claimed process results in "improvements in diagnosis without adding undesirable computational complexity via the designation of too many clusters" (Appeal Br. 9–10), there is no argument or

evidence demonstrating that the *claimed* process provides for computers to do what could not be done previously, in contrast to the facts in *McRO*.

As noted above, the method collects information and analyzes it but does nothing to change its character as collected information; the collected information is simply organized in a particular way for display.

Furthermore, "the use of generic computer elements like a microprocessor or user interface do not alone transform an otherwise abstract idea into patent-eligible subject matter." FairWarning IP, LLC v. *Iatric Sys., Inc.*, 839 F.3d 1089, 1096 (Fed. Cir. 2016). The system claims here are unlike those in DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1257 (Fed. Cir. 2014), where the Court found the claims that included a computer process programmed in a particular way to carry out a particular function included an inventive concept in modification of conventional mechanics behind website display to produce dual-source integrated hybrid display. And the claims here are unlike the "data storage and retrieval system" claims in Enfish, 822 F.3d at 1336, 1339 where the Court found the claims that included "means for" executing certain things included an inventive concept in improving "the way a computer stores and retrieves data in memory." And the claims are unlike the system claims in *Bascom* Global Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341, 1350 (Fed. Cir. 2016), where the Court found the claims included an inventive concept in the ordered combination of system components including a local client computer and a remote ISP server connected to the client computer and Internet computer network providing for "the installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user."

Thus, contrary to Appellants' arguments (see Reply Br. 6–8), we find that the claim limitations, analyzed alone and in combination, fail to add "something more" to "transform" the claimed abstract idea of collecting and analyzing information to determine a diagnosis, prognosis, or a response to treatment into "a patent-eligible application." *See Alice*, 134 S. Ct. at 2354, 2357.

c. Pre-emption

Appellants argue that the claims should not be found to be patent ineligible under 35 U.S.C. § 101 because the claimed invention does not "pre-empt others from utilizing ideas necessary for future innovation in other technology fields," contending that "[o]ther parties are still free to use clustering for other techniques and/or in other fields of endeavor, for example." (Appeal Br. 8.) Appellants further contend that the limitations are "tied to specialized image acquisition machines and imaging hardware" and "there is no reasonable interpretation whereby these claims could be viewed as attempting to 'tie up' an abstract concept in its entirety." (Reply Br. 4–5.) We do not find either point persuasive. "[T]he absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). "Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot." *Id*.

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Obviousness

The Examiner finds that Gough teaches a method and system as claimed except that while Gough teaches classifying cells from multiplexed

cellular images into response classes, it does not teach the delineation and segmenting of individual cells into compartments. (Ans. 3–4.) The Examiner finds that Hunter teaches a method of analyzing cellular fluorescence micrographs where the fluorescent signals are indicative of the amount and location of various biomarkers within each cell. (Ans. 4.) The Examiner further finds that the images are segmented into individual cells and cellular compartments and can be used for measuring cytological characteristics. (Ans. 5.) The Examiner concludes that it would have been obvious to one of ordinary skill in the art to "combine the image analysis teachings of Hunter — in which individual cells are delineated and segmented into compartments — with the cell profile analysis method of Gough, because Gough teaches creating a cell profile based on image features, but does not actually teach how to calculate those image features." (Ans. 6.)

We agree with the Examiner's factual findings and conclusion of obviousness.

Appellants argue that neither Gough nor Hunter disclose generating and displaying "a montage" as required by claims 1 and 17 because Gough's separate images from each channel of a multiplexed high content screen, are not "a series of superimposed or juxtaposed portions" of the multiplexed biometric images, and there is no indication in Gough that the images are "displayed." (Appeal Br. 11–12 (emphasis added); Reply Br. 8.) First, we note that the claimed method does not require the montage be a series of superimposed or juxtaposed portions of the multiplexed images. Rather, the method requires the montage "comprises a portion of a plurality of the multiplexed biometric images of the first cell's expression of the plurality of

biomarkers [with respect to a field of view]." We agree with the Examiner that a set of juxtaposed images such as provided in Gough's Figure 6 meets the claimed montage requirement. We also agree with the Examiner that the images of Gough's Figure 6 meet the "field of view" requirement because a field of view can simply be "the area of the microscopic sample captured by an image" (Ans. 9 (citing Spec. ¶ 54)). It is well known in the art to take images of the same physical portion of the sample using different biomarkers. (*See*, *e.g.*, Gough ¶¶ 41, 48–50, 58–59, 73, 78–79, 89, 160, 166–86, 207–26.)

Second, as to the requirement that the images be "displayed," we find no compelling argument by Appellants establishing that the images provided in Figure 6 of Gough are not "displayed." Gough provides images of "multiplexed labeling of cells with a panel of biomarkers" that are "from each channel of a multiplexed high content screen." (Gough ¶¶ 24 and 85 (describing what Figure 6 is)). Moreover, Gough teaches that the "the panel of fluorescently labeled reagents indicate the presence, amount, location, activity, distribution, or combination thereof, of the biomarkers in the fluorescently labeled section and that this is part of the collected data of the cellular systems biology profile that is stored in a database for reference" and that "[v]arious methods can be used to compare the cellular systems biology profile of the one or more further samples and the cellular systems biology profile in the database, such as by graphical display, cluster analysis, or statistical measure of correlation and combinations thereof" (Gough ¶¶ 46–47) (emphasis added) which "permits the identification of similarities, differences, or a combination thereof, of the cellular systems biology profile of the one or more further samples and the reference cellular

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systems biology profile" (Gough \P 46). The foregoing suggests that Gough teaches displaying images which would permit comparisons to be made.

Appellants further argue that Gough and Hunter do not disclose "assigning respective individual cells in the field of view to respective single clusters" because "Gough's clustering of heterogeneous cells does not appear to be field-of-view based." (Appeal Br. 12–13.) We agree with the Examiner that Appellants' argument is not persuasive. As discussed above, "field of view" is interpreted to be the area in which the digital image is obtained. And Gough teaches assessing a percentage of specific cells in the specimen examined determined by their respective labels. (*See, e.g.*, ¶¶ 215–26.) As the Examiner notes, Appellants' Specification indicates that "the 'attributes' on which the cells are clustered are image features such as 'a nucleus intensity ratio' (0063) and other intensities that indicate biomarker expression (0064)." (Ans. 10.) As the Examiner further explains:

Gough teaches that each cell from the sample is separately classified into a single "response class" (0095). Since the classification is performed on the basis of features extracted from the images (0031, 0032; see also Hunter 0076), and since each image is equivalent to "an individual field of view", Gough teaches that the cells "in the field of view" are assigned to clusters. . . . [and] Gough teaches that the clustering algorithm is particularly useful for resolving the cellular heterogeneity of tissue composition (0095), further indicating that one of the advantages of the clustering algorithm is that it can assign different cells in a single image to different cell clusters. So Gough teaches the contested limitation.

(*Id.* 10–11.)

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Claims 2, 6–15, 18, and 21–30⁶ have not been argued separately and, therefore, fall with claims 1 and 17. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection of claims 1, 2, 6–15, 17, 18, and 21–30 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

We affirm the rejection of claims 1, 2, 6–10, 13–15, 17, 18, 21–25, and 28–30 under 35 U.S.C. § 103(a) as unpatentable over Gough and Hunter.

We affirm the rejection of claims 11, 12, 26, and 27 under 35 U.S.C. § 103(a) as unpatentable over Gough, Hunter, and Theodoridis.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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⁶ Appellants assert that "claims 11, 12, 26, and 27 are believed to be allowable on the basis of its dependency from an allowable base claim, as well as for the subject matter separately recited in these claims." (Appeal Br. 13.) Such an argument is not sufficient as a separate argument for patentability of these claims. *In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) (noting that separately arguing a claim requires "more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art.")